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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,844	04/21/2004	Charles W. Alvord	30392.00	5306

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KNOXVILLE, TN 37950-1295

EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,844	ALVORD ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,10,14,15,22,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,10,14,15,22,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 5 May 2005 does not place the application in condition for allowance.

Status of Objections and Rejections Pending Since the Office Action of 14 December 2004

2. All objections and rejections of claims 3-9, 11-13, 16-21, 23, 24, and 27-37 are obviated due to cancellation of the claims.

3. The objection to various claims for using the term "charge particle detector" is withdrawn due to Applicant's amendment.

4. The rejection of claims 1, 10, and 25 under 35 U.S.C. §102(e) as anticipated by Burns et al is withdrawn due to Applicant's amendment.

5. The rejection of claims 1, 2, 10, 14, 15, 22, 25, and 26 under 35 U.S.C. §103(a) as unpatentable over Wiktorowicz et al in view of Tokita et al and Karmen is withdrawn due to Applicant's amendment.

Specification

6. Clarification regarding the embodiment of Figure 8 is respectfully requested. Well 30' is referred to in the specification as a collimation well, but the detector (Electrodes 50' and silicon detector material) are disclosed and illustrated as being deposited within the well, and occupying its entire depth. (Figure 8 and Paragraphs

0041 and 0042) It is unclear how any collimation effect could be achieved with this structure. It appears that this structure would simply detect any incident beta particles without any filtering based on angle, other than that provided by the thickness of the surrounding base.

Claim Objections

7. Claim 1 is objected to because of the following informalities: In lines 9 and 11, a "charge charged particle detector" is recited, although a "charged particle detector" was intended. Also, in line 14, "said charged particle" is recited, although "said charged particle detector" was apparently intended. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 2, 10, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al in view of Koehler.

Regarding claim 1, Burns et al disclose a detector assembly, comprising a base with a microfluidic channel formed in the base allowing fluids to flow therethrough. (Figure 1); a window formed in the base; a solid state charged particle detector integral with the base, wherein the window is positioned between the detector and the channel, and the window has a thickness sufficient to allow beta particles through to be detected.

(Fabrication described at Column 31, line 43 - Column 32, line 38; window would comprise thermal SiO_2 and baked photoresist layers described at Column 32, lines 23-32, detector is disclosed as being fabricated beneath the channel at column 32, lines 5-8) Since the window thickness of the detector is sufficient to allow negative beta particles to pass, it would also allow positrons to pass.

Regarding claims 2, 25, and 26, the portions of the silicon base adjacent the 10 micron wide detector (In region E as illustrated in Figure 1) would have a thickness relative to the direction of incoming radiation from decay events occurring upstream or downstream from the detector to substantially attenuate beta particle transmission, and thereby increase the linear resolution of the device. (i.e. only decay events occurring over the detector will be detected)

Regarding claims 10 and 25, the base of the device of Burns et al comprises silicon. (Column 31, lines 45-47)

Burns et al do not explicitly describe the locations of the electrodes of their detector, only describing that contact holes are etched to the appropriate region and pads were subsequently formed. (Column 32, lines 23-30)

Koehler discloses a radiation detector that is similarly based on a semiconductor p-n junction formed on a wafer, and shows electrodes positioned on either side of the base. (Figure 5, Electrode 13, grounding of the p-side illustrated on the opposite side)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Burns et al by forming electrodes on opposite faces of the base, as taught by Koehler, because one having ordinary skill would have recognized that electrodes could be provided at any convenient point on the device body - it is a simple matter of design choice well within the level of ordinary skill in the art. Koehler demonstrates the suitability of forming contacts on opposite sides of a wafer in devices of this type, and the silence of Burns et al indicates that a skilled artisan would have been able to choose the positioning of the electrodes. Such a skilled artisan would have looked to prior art examples, such as Koehler, in deciding electrode positioning.

Specific to claim 1, in this combination, the window would inherently be positioned as claimed, as the electrodes would be on either surface of the wafer, and the window would lie between the surfaces.

10. Claims 1, 2, 10, 14, 15, 22, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktorowicz et al in view of Tokita et al, Kanbara et al, and Karmen. A translation of Tokita et al is provided with this action, only the figures and English abstract of Kanbara et al are relied upon explicitly.

Regarding claims 1, 14, and 25:

Wiktorowicz et al disclose a microfluidic assembly, comprising a base (Figure 4, plates 120 and 122); and microfluidic channels formed in the base allowing fluids to flow

therethrough. (Figure 4, 170; Column 8, lines 6-27) (Column 6, lines 15-19 and 24-26; Column 16, lines 43-49)

Wiktorowicz et al do not explicitly disclose a detector assembly comprising a window of any type formed in the base, or a solid-state charged particle detector supported by the base wherein the window is interpositioned between the charged particle detector and the channel.

Tokita et al disclose a particle detecting assembly comprising a radiation detector (Figures 1 and 2, detectors 5a-5d) supported by a base (Cassette with plates 1a and 1b) that is a multilane electrophoresis cassette similar to that of Wiktorowicz et al, wherein a window is formed in the base (Figure 2, Slit 4), wherein the window has a thickness sufficient to allow transmission of beta particles from phosphorus-32. (See abstract; Translation, Page 5, 1st paragraph) Since the window thickness of the detector of Tokita et al is sufficient to allow negative beta particles to pass, it would also allow positrons to pass.

Tokita et al do not explicitly disclose using a solid-state particle detector or a detector with electrodes positioned as claimed.

Kanbara et al disclose a particle detecting assembly similar to that of Tokita et al, in which a detector is positioned on either face of the electrophoresis plate. (Figures 4 and 5; windows 13 described in the abstract as allowing the beta particles to pass from the analyte to the detector, so a detector on either face would necessarily be present)

Kanbara et al do not explicitly teach using solid-state detectors.

Karmen teaches the suitability of using solid-state particle detectors in place of other types of radiation detectors. (e.g. Geiger counters, photomultiplier tubes with scintillators, gas detectors) (Column 3, lines 4-12; Column 5, lines 1-55) Typical solid-state detectors (e.g. silicon p-n junction type) would be fully capable of detecting positrons as well as negative beta particles, and each would require appropriate electrodes for signal transmission.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wiktorowicz et al by adding a particle detector of the type used by Tokita et al (i.e window/spacer 3, slit 4, detector 5) because it would provide digital data for more facile analysis, compared to the phosphor plates suggested by Wiktorowicz et al in the case of radioactivity detection. (Column 16, lines 46-47) In general, Wiktorowicz et al do not specify any preferred type of detector, instead suggesting a range of suitable types. (Column 16, lines 40-56)

It would further have been obvious to modify the combination of Wiktorowicz et al and Tokita et al by providing a second detector for the detection device, positioned on the opposite face of the electrophoresis plate, as taught by Kanbara et al, because one having ordinary skill in the art would have recognized that nuclear decay has no preferred direction, and having a second detector would double the detected signal, allowing detection of smaller or more dilute samples.

It would further have been obvious to modify the combination of Wiktorowicz et al, Tokita et al, and Kanbara et al by specifically using solid state radiation detectors, as taught by Karmen, because it would provide a rugged system with high sensitivity and minimal complexity.

Since the solid state detectors require electrodes to function, a detection system that comprises two detectors disposed on opposite sides of the electrophoresis plate in the configuration taught by Kanbara would meet the limitations for electrode placement, as a first electrode of the first detector would be disposed on a first side of the base, and a second electrode of the second detector would be disposed on the second side of the base, spaced from the first side. Such a detection system would read on the recited "charged particle detector".

The limitation in the preambles of claims 1, 14, and 25, "for quantifying concentration of positron emitters" and recitation of "positron emitters" in defining the thickness of the window are not considered to limit the scope of the claim such that positron emitters must be present in the device, as it merely involves the intended use of the device. "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Regarding the limitation in claim 1 that the detector be integral with the base, in *In re Larson*, the court affirmed a rejection of claims to a device with integral components over a prior art device with rigidly secured components, holding, among

other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice." *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) The particle detectors recited in the prior art presented in the rejections above would certainly have to be rigidly secured, in order for accurate detection. Therefore, the examiner considers making the detectors integral to the base to be a modification that would have been obvious to one having ordinary skill in the art at the time the invention was made.

Relevant to claim 14, collimation means are disclosed (Slit 4) by Tokita et al and would be present and proximate the microfluidic channel in the combination described above.

Relevant to claim 25, the window (Spacer 3) of Tokita et al increases the linear resolution of the device by allowing the radiation to pass, as opposed to the surrounding area, which would attenuate the signal. Also relevant to claim 25, Wiktorowicz et al disclose using glass or plastic plates. (Column 6, lines 15-26)

Addressing the dependent claims:

Relevant to claims 2, 15, and 26, Tokita et al disclose a portion of the base adjacent the window and supporting the detector having a thickness sufficient to attenuate the beta particles, which would increase linear resolution, since only particles emitted through the window region would be detected. (Thick portion of plate 1a adjacent the window, e.g. Figure 2a)

In incorporating the detector of Tokita et al into the cassette of Wiktorowicz as described above, these aspects of the detector would necessarily be incorporated into the combination.

Relevant to claims 10 and 22, Wiktorowicz et al disclose glass or plastic plates. (Column 6, lines 15-26)

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Regarding the lack of a translation of Tokita et al, noted by Applicant at Page 10, 2nd full paragraph, a certified translation of this reference is provided with this Office Action. A translation of Kanbara et al will be prepared, but the disclosure of the figures and English abstract of this reference is believed to be sufficient for the rejections made above.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
July 19, 2005

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